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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,022	07/14/2006	Yasuhiro Nakano	P29235	9439
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EXAMINER BASS, DIRK R				
ART UNIT 1797		PAPER NUMBER		
NOTIFICATION DATE 05/04/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/567,022

Applicant(s)

NAKANO ET AL.

Examiner

DIRK BASS

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-13, 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed January 26, 2010 is acknowledged. Claims 1-6, 10-13, 15, and 16 are pending. Claim 10 is amended, claim 13 is cancelled, and claims 17-20 are newly added. Claims 1-6, 10-13, and 15-20 are pending and further considered on the merits.

Response to Amendment

In response to the amendment, the examiner withdraws the 35 U.S.C. 112 first and second paragraph rejections and maintains the 35 U.S.C. 103(a) rejections set forth in the previous office action.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. **Claims 1-6 and 17-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., JP 2003-149096 (Tanaka) in view of Morikawa et al., USPA 2003/0150808 (Morikawa) as evidenced by Tanaka et al., USPA 2006/0097361 ('361) and Koo et al., US 4992485 (Koo).
3. Regarding claims 1-5, Tanaka discloses a porous membrane made of organic polymer (Ex. 1-5) for use in blood filtration (Fig. 3, Para. 1) cast on a substrate (Para. 28), wherein the porous membrane (Fig. 3, Para. 1) has an average pore diameter of 0.5 to 20 μm (Para. 19), where it is inherent that the pore diameter has a standard deviation that falls within the range of 0 to 0.6 μm , as the standard deviation encompasses a range that includes values higher than the claimed diameter (Para. 32). It appears based on the photomicrograph of TANAKA (Figs. 4-5) and the implicit, well-known structural nature of honeycombed membranes, that the membrane has an opening ratio between 15% and 80%; percentage of through-pores to all the pores of the porous membrane of 30% or more; and a structure in which pores adjacent to one another communicate, as further evidenced by '361 which discloses a side-view of the well-known honeycombed membrane structure (Fig. 2).
4. TANAKA does not appear to expressly disclose having the porous membrane cast onto and penetrating a porous support forming a composite membrane; however it

is well known to have honeycomb membranes with well defined pore structures cast (penetrating) a porous support to improve performance and enhance durability for filtration applications, as disclosed by MORIKAWA. MORIKAWA discloses casting an organic resin forming a porous membrane onto a porous substrate (Ex. 1,2, Fig. 6) to enhance durability of the membrane during filtration (Pg. 1, Para. 4-5). MORIKAWA further discloses that the membrane thickness to pore diameter ratio is in the range of 0.05 to 2 (referring to macrovoid diameter) and average membrane thickness of 0.1 to 20 μm (Ex. 1-2, Comp. Ex. 4), where it is inherent that the standard deviation of membrane thickness would fall within the standard deviation disclosed, as the range includes values higher than the claimed thickness.

5. At the time of the invention it would have been obvious to a person having ordinary skill in the art to cast the porous membrane of TANAKA on the porous support of MORIKAWA. The motivation to have a composite membrane comprising a honeycomb membrane penetrating a porous substrate would have been to reduce pressure loss during filtration, improve fluid flow and have a composite membrane with enhanced durability (KOO, C2/L39-59).

6. As to Claim 6, TANAKA in view of MORIKAWA discloses the composite porous membrane, where it is inherent that the porous membrane can be used to culture cell solutions, absent evidence to the contrary. As it has been held that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

7. Claim(s) 17-20 recite limitations regarding manipulative steps to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

8. **Claims 10-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka in view of Morikawa as applied to claims 1-6, and in further view of Sheik-Ali, US 6645388 (Sheik-Ali).

9. As to Claims 10 and 12-13, TANAKA in view of MORIKAWA discloses a leukocyte removal filter device (TANAKA, Para. 1); a plurality of filter elements (TANAKA, Para. 19) and the composite membrane for use in the leukocyte depletion medium as shown in the 103(a) rejection of Claim 1.

10. TANAKA (in view of MORIKAWA) does not appear to expressly disclose a prefilter (first filter) at the entrance of the suspension. However, SHEIKH-ALI discloses a prefilter in leukocyte depletion device at the entrance capable of removing leukocytes (C7/L27-30) prior to the other filtration elements at the exit side. At the time of the invention it would have been obvious to a person having ordinary skill in the art to include the prefilter of SHEIKH-ALI in the leukocyte removal device of TANAKA (in view of MORIKAWA). The motivation would have been to remove gel particulates from the hemocyte suspension to improve filtration efficiency.

11. It would have been obvious to a person having ordinary skill in the art that the composite membranes of TANAKA (in view of MORIKAWA) have a higher effective filtration area (based an increased porosity and uniform pore size) and therefore requires a lesser volume of filter material to obtain the desired degree of leukocyte removal. It is desirable to have a lower filter volume as it reduces the amount of fluid retained in filter medium. Therefore, it would have been obvious to optimize the volume of the filter element to have a volume between 2 and 18 cm³ as it has been held obvious to optimize a result effective variable. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

12. As to Claim 11, SHEIKH-ALI discloses that in order to achieve the desired leukocyte depletion it is necessary to have an effective area of the filter between 4 and 300 cm² (C7/L36-37).

13. **Claims 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi et al., US 5665596 (Mussi) in view of Tanaka and Morikawa as relied upon in the rejection of claim 1, and evidenced by Shimomura et al., JP 2001-157574 (Shimomura).
14. As to Claims 15-16, MUSSI discloses a cell co-culture device (Fig. 1-4) which divides different cell groups and allows them to come into contact with each other (C4/L50-55); integrated cup-type culture container (12); tube having the cell culture diaphragm adhered to one end (14); and container which can hold the cup-type culture container and culture solution (Fig. 3).
15. MUSSI does not appear to expressly disclose using the membrane of TANAKA in view of MORIKAWA as shown in the rejection of Claim 6 above. However at the time of the invention it would have been obvious to a person having ordinary skill in the art to use the composite membrane of TANAKA in view of MORIKAWA in the apparatus for cell co-culturing as it is well known that the honeycombed membrane structure is better for cultivating cells (SHIMOMURA, Para. 1, 7-10). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

16. Applicant's arguments filed January 26, 2010 have been fully considered but they are not persuasive.
17. In response to applicant's argument that Morikawa is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the cited prior art is reasonably pertinent to the particular problem with which the applicant is concerned, namely enhancing the durability of a membrane during filtration. Furthermore, the examiner considers Morikawa to also be in the same field of applicant's endeavor, as they both pertain to particulate filtration devices.
18. Applicant's arguments concerning the manner in which the filter device is made are not persuasive since the examiner considers such limitations to be manipulative

steps to bring about a specific product. Even though product-by-process limitations are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113). The examiner reminds applicant that claim 1 merely recites a "porous membrane penetrates into at least a *portion* of the surface", thereby allowing the combination of Tanaka and Morikawa to obviate claim 1.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass